

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte PHILLIP A. FURMAN, JR. and GEORGE R. PAINTER, III

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Appeal No. 96-0965  
Application 08/054,548<sup>1</sup>

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH and ROBINSON, Administrative Patent Judges

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claim 8, which is the only claim pending in the application.

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<sup>1</sup>Application for patent filed April 27, 1993. According to Appellants, this application is a divisional of application 07/846,367, filed March 5, 1992, now U.S. Patent 5,234,913, issued August 10, 1993.

### THE APPEALED CLAIM

The appealed claim reads as follows:

8. A method for inhibiting the replication of the human immunodeficiency virus which comprises administering to cells containing said virus a first compound CIS-1-(2-(hydroxymethyl-1,3-oxothiolin-5-yl)-6-fluorocytosine or a pharmaceutically acceptable salt thereof and a second compound 3'-azido-3'-deoxythymidine, the first and second compounds being present in an amount to provide a synergistic combination.

### PROCEDURE

The examiner's presentation of this appeal represents somewhat of a procedural quagmire. In the first place, page 2 of the Examiner's Answer is missing from the record. Secondly, page 3 of the Answer is internally inconsistent. In section (7), the examiner expressly states that no prior art references are relied on in rejecting the claim under appeal. Nevertheless, in section (8), the examiner states that "[t]he following references are provided in support of the Examiner's position regarding the rejection under 35 U.S.C. § 112, first paragraph." The examiner cites these references: Hitchcock, "In Vitro Antiviral Activity of Didanosine Compared with That of Other Dideoxynucleoside Analogs Against Laboratory Strains and Clinical Isolates of Human Immunodeficiency Virus", Clinical Infectious Diseases, vol. 16(Suppl. 1) pgs. S16-S21, published 1993 by the University of Chicago; Gallicchio et al. ( Gallicchio), "Increased

Hematopoietic Toxicity Following Administration of Interferon -  $\alpha$  With Combination Dideoxynucleoside Therapy (Zidovudine Plus DDI) Administered in Normal Mice", Life Sciences, vol. 56 no. 3, pgs. PL71-81 (1995); and "Virus sidesteps convergent therapy", Treat. Issues, vol. 9, no 1, pg. 6 (Jan. 1995). This is confusing, because it is unclear whether the examiner is, or is not, relying on prior art references to establish that the appealed claim is unpatentable.

Adding to the confusion, section (9) of the Examiner's Answer is entitled "Grounds of rejection", but no grounds of rejection are set forth therein. There, the examiner objects to the specification under 35 U.S.C. § 112, first paragraph, "as failing to provide an enabling disclosure for the scope of the invention as claimed". The reasons for this objection are set forth in the Answer, page 4, first full paragraph. According to the examiner, Appellants' specification describes the use of both compounds recited in claim 8, in combination, to achieve a synergistic effect in inhibiting HIV in cells in vitro. The examiner argues, however, that claim 8 is not limited to in vitro use, and that predicting synergistic efficacy in vivo from Appellants' in vitro results would not have been accepted by any person skilled in the art. Later, in section (11) of the Examiner's Answer, entitled "Response to argument", the examiner states

that "[c]laim 8 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification (emphasis added)." See page 8, second full paragraph, of the Examiner's Answer.

The Hitchcock , Gallicchio , and "Virus sidesteps convergent therapy" references, cited above, are not positively included in the statement of the examiner's rejection. As stated in In re Hoch 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407, n.3 (CCPA 1970),

Where a reference is relied on to support a rejection, whether or not in a "minor capacity," there would appear to be no excuse for not positively including the reference in the statement of the rejection.

Where, as here, the Hitchcock, Gallicchio, and "Virus sidesteps convergent therapy" references are not included in the statement of rejection under 35 U.S.C. § 112, first paragraph, and where the examiner expressly states that no prior art references are relied on in setting forth the rejection, we shall not consider these references further.

In the Final Rejection (paper no. 8), page 2, the examiner rejected claim 8 under 35 U.S.C. § 101 "because the claimed invention has no demonstrated utility for use in vivo." According to the examiner, the specification teaches that combinations of the compounds recited in claim 8 have been tested for anti-HIV activity in vitro. The

examiner argued, however, that the claim is not limited to providing a synergistic effect in

vitro, and that the specification's in vitro results are not correlative or predictive of a synergistic effect in vivo. However, the examiner does not repeat or refer to the rejection under 35 U.S.C. § 101 in the Examiner's Answer. The only plausible interpretation which these facts permit is that the rejection under 35 U.S.C. § 101 has been dropped. See Paperless Accounting, Inc. v. Bay Area Rapid Transit System, 804 F.2d 659, 663, 231 USPQ 649, 652 (Fed. Cir. 1986). The sole issue on appeal is whether the examiner erred in rejecting claim 8 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure.

#### THE MERITS

The first paragraph of 35 U.S.C. § 112 states that

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention (emphasis added).

This provision calls into play the "how-to-make" and "how-to-use" requirements of the statute. In our judgment, Appellants' specification is replete with information teaching persons skilled in the art how to make and how to use the claimed invention.

The specification teaches that the first and second compounds recited in claim 8

may be administered simultaneously or sequentially (page 6, second paragraph; paragraph bridging pages 6 and 7). In the specification, Appellants teach the optimum molar ratios of the compounds recited in claim 8 (page 7, second full paragraph). Appellants also describe suitable dose ranges of the claimed combination (paragraph bridging pages 7 and 8); suitable modes of administration (page 7, lines 3 through 7; page 8, first full paragraph); and suitable pharmaceutical formulations (page 8, first full paragraph through page 10, fourth paragraph). In the specification, paragraph bridging pages 10 and 11, Appellants teach the preparation of zidovudine. Appellants also describe alternative methods for preparing the other compound recited in claim 8 (pages 11 through 14). Further, Appellants provide detailed information respecting tablet formulations, capsule formulations, injectable formulations, and intramuscular injection formulation, a syrup, a suppository, and pessaries (pages 16 through 22). Example 8 in the specification (page 23) is a working example describing the preparation of 1-(2-(hydroxymethyl)-1,3-oxathiolan-5-yl)-5-fluorocytosine. Finally, Appellants set forth a working example describing the in vitro synergistic effect of the compounds recited in claim 8. (pages 24 and 25).

All in all, we believe that the specification imparts ample information to persons

skilled in the art, enabling them to make and use the claimed invention. Nor does the examiner directly attack the specification on how-to-make and/or how-to-use grounds. Rather, it appears that the position espoused by the examiner under 35 U.S.C. § 112, first paragraph, is the very same position dropped under 35 U.S.C. § 101. According to the examiner, Appellants' specification describes using the claimed composition for inhibiting HIV cells in vitro; but in vitro data is not predictive of a synergistic effect in vivo. In other words, the examiner would "backdoor" a rejection of claim 8 under 35 U.S.C. § 101 couched in terms of 35 U.S.C. § 112, first paragraph.<sup>2</sup>

The record reflects that (1) the combination of first and second compounds, recited in claim 8, provides a synergistic effect when tested for anti-HIV activity in vitro (specification, pages 24 and 25); (2) zidovudine (AZT) is a commercially available product, known for treating HIV in vivo in humans; (3) the other compound of claim 8 is also disclosed for use in treating HIV in vivo (U.S. Patent No. 5,210,085, issued May 11, 1993 to Liotta et al.); and (4) parent application Serial No. 07/846,367 issued as

U.S. Patent No. 5,234,913 on August 10, 1993, claiming a pharmaceutical composition

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<sup>2</sup> As previously indicated, the Final Rejection included separate rejections of claim 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. Both rejections were based on essentially the same reasoning. In the Examiner's Answer, the examiner dropped the rejection under 35 U.S.C. § 101 and carried forward the rejection under 35 U.S.C. § 112, first paragraph.

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containing Appellants' first and second compounds and supported by the same specification which here supports claim 8. In view of the foregoing, we disagree with the examiner that Appellants' in vitro data is not predictive of a synergistic effect in vivo for the combination of first and second compounds recited in claim 8.

The rejection of claim 8 under 35 U.S.C. § 112, first paragraph is reversed.

REVERSED

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
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	)	
	)	BOARD OF PATENT
WILLIAM F. SMITH	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
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DOUGLAS W. ROBINSON	)	
Administrative Patent Judge	)	

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